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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,201	03/31/2006	Hiroyuki Sugawara	1034509-000002	8956
21839 7590 01/25/2008 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER MARCETICH, ADAM M	
			ART UNIT 3761	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/574,201

Applicant(s)

SUGAWARA, HIROYUKI

Examiner

Adam Marcetich

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20, 21 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20, 21 and 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/JP04/14203, filed on 29 September 2004.

Response to Amendment

2. Acknowledgment is made of Applicant's amendments filed 25 September 2007.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (US Patent 5,180,504).
5. Regarding claim 31, Johnson discloses a filter unit as substantially claimed, see discussion of claim 20. Johnson further discloses a tube not being connected to a container between the first and second ends of the tube (column 7, lines 47-59, especially lines 47-50 and Fig. 6, vent line 63 as labeled in Fig. 4). Johnson further discloses tubing made from PVC (column 4, lines 42-46), a plastic capable of being cut, melted and aseptically connected. Therefore, filtration device 40 of Johnson is adapted

to be put to use by cutting the tube between the first and second ends to result in cut ends of the tube and aseptically connecting the cut ends of the tube to another tube.

Claim Rejections - 35 USC § 102 / 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 14-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson et al. (US Patent 5,180,504).

8. Regarding claim 14, Johnson discloses a filter unit to be aseptically connected to a connected bag set in order to assemble a blood treatment circuit, said connected bag set having previously been sterilized, being composed of a primary bag holding collected blood (column 4, lines 13-24 and Fig. 6, primary bag 16);

a secondary bag holding blood or blood components (column 7, lines 15-22 and Fig. 6, transfer bag 34),

a first tube to connect said primary bag to said secondary bag (column 6, lines 51-60 and Fig. 6, tubing 68),

which comprises said filter unit comprising an inlet and an outlet (Fig. 6, filtration device 40 having upper and lower ends),

a filter medium to remove specific components from fluid introduced through said inlet (column 6, lines 14-19 and Fig. 2, filtration medium 44), and

a second tube, both ends of which are connected to said inlet and said outlet (column 7, lines 47-59, especially lines 47-50 and Fig. 6, vent line 63 as labeled in Fig. 4).

Regarding the limitation of "using an apparatus for aseptically connecting tubes," Examiner notes that the claim is directed to a filter, not a method of connecting. Because of the nature of product-by process claims, the Examiner cannot ordinarily focus on the precise difference between the claimed process of putting a filter to use and the disclosed filter. It is then Applicants' burden to prove that an unobvious difference exists. See *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983).

In the instant case no Graham vs. John Deere analysis was made but rather the test set out in MPEP 706.03(e) and *In re Marosi* was applied while explaining why the claimed product does not patentably distinguish over the prior art under 35 USC 102/103.

9. Regarding claim 15, Johnson discloses a filter and connector system as discussed for claims 5 and 6. Connection devices 66a and 66b substantially mark a connection position between first and second tubes.

10. Regarding claim 16, Johnson discloses a filter and connector system as previously discussed for claim 1. The connector of Johnson is capable of showing which direction fluid flows through the connector, by printing or drawing on the connector.

Regarding rationale and motivation, see discussion of claim 9.

11. Regarding claim 17, Johnson discloses a filter and connector system as discussed for claim 1. The connector system of Johnson is also capable of showing a correct connection between first and second tubes as discussed for claim 10.

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims 1, 2, 5, 6, 9-11, 18, 21 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US Patent 5,180,504) in view of Spencer (US Patent 4,369,779).

14. Regarding claim 1, Johnson discloses a method for assembling a blood treatment circuit by aseptically connecting:

a connected bag set, which has previously been sterilized (Fig. 6, primary bag 16 and transfer bag 34), and

a filter unit, which has previously been sterilized (column 6, lines 14-19 and Fig. 2, filtration device 40),

to each other (Fig. 6, primary bag 16, transfer bag 34 depicted as connected to each other through fluid path 36),

said connected bag set being composed of:

a primary bag holding collected blood (column 4, lines 13-24 and Fig. 6, primary bag 16); and

a secondary bag holding blood or blood components (column 7, lines 15-22 and Fig. 6, transfer bag 34), and

a first tube to connect said primary bag to said secondary bag (column 6, lines 51-60 and Fig. 6, tubing 68),

said filter unit having an inlet and an outlet (Fig. 6, upper and lower ends of filtration device 40),

a filter medium to remove specific components from a fluid introduced through said inlet (column 6, lines 14-19 and Fig. 2, filtration medium 44), and

a second tube, both ends of which are connected to said inlet and said outlet (column 7, lines 47-59, especially lines 47-50 and Fig. 6, vent line 63 as labeled in Fig. 4),

Johnson discloses the invention as substantially claimed, see above. However, Johnson lacks steps of cutting and connecting first and second tubes as claimed [claim 1]. Spencer discloses a process of cutting and aseptically connecting tubes first and second tubes (column 4, lines 18-31 and column 6, lines 10-26; Fig. 1, hot cutting means 19 cutting and connecting tubes 11 and 12 at molten tube interfaces 21 and 24). Spencer provides the advantage of quick and aseptic connection (column 6, lines 48-53, about 5 seconds for cooling). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Johnson as discussed with the cutting and connecting steps as taught by Spencer in order to provide quick and aseptic connection between medical tubing.

Since the circuit must be assembled in order to function, Johnson substantially provides a method of assembling the circuit.

15. Regarding claim 2, Johnson discloses a method for assembling a blood treatment circuit, said method comprising:

sterilizing a connected bag set which is composed of a primary bag holding collected blood (column 4, lines 13-24 and Fig. 6, primary bag or container 16); and
a secondary bag holding blood or blood components (column 7, lines 15-22 and Fig. 6, transfer bag 34); and

a first tube to connect said primary bag to said secondary bag (column 6, lines 51-60 and Fig. 6, tubing 68);

sterilizing a filter unit having an inlet and an outlet, a filter medium to remove specific components from a fluid introduced through said inlet (column 6, lines 14-19 and Fig. 2, filtration device 40 having filtration medium 44), and

a second tube, both ends of which are connected to said inlet and said outlet (column 7, lines 47-59, especially lines 47-50; Fig. 6, vent line 63 as labeled in Fig. 4);

Johnson further discloses the entire system as being a sterile system (column 6, lines 30-36).

Johnson discloses the invention as substantially claimed, see above. However, Johnson lacks steps of cutting and connecting first and second tubes as claimed [claim 1]. Spencer discloses a process of cutting and aseptically connecting tubes. Regarding rationale and motivation, see discussion of claim 1.

16. Regarding claims 5 and 6, Johnson discloses a connector system, which substantially marks a connection position (column 6, lines 61-68 through column 7, lines 1-14 and Fig. 6, sterile connection devices 66a and 66b).

17. Regarding claim 9, Johnson discloses a connector system as previously discussed for claims 5 and 6. The connector of Johnson is capable of showing which direction fluid flows through the connector, by printing or drawing on the connector. Examiner takes official notice that markings to show directional flow are well known in the art. For example, Teirstein (US Patent 5,779,666) uses arrows to indicate flow directions in one-way valves (Fig. 2, elements 36 and 58).

18. Regarding claim 10, Johnson discloses a method of assembling as previously discussed for claims 5 and 6, comprising connection devices 66a and 66b. With regard to a mark, the connectors form a correct connection after heating (column 7, lines 3-14), substantially forming a mark that indicates correct connection. When the connectors of Johnson are heat-sealed, a correct connection is formed. Therefore, the connection devices 66a and 66b are inherently capable of indicating that the tubes have been correctly connected as claimed. The markings effectively extend to both first and second tubes of Johnson as depicted (Fig. 6, connection devices 66a and 66b extending to tubing 68 and vent line 63).

19. Regarding claims 11 and 18, the language "formed by expanding" represents a product-by-process limitation. Johnson discloses the invention as substantially claimed, see above. However, Johnson lacks an expanded outside diameter of first and second tubes as claimed [claims 11 and 18]. Spencer discloses an expanded outside diameter

of first and second tubes (column 5, lines 35-38 and Fig. 9, fused molten interfaces 21' and 24'). Spencer provides the advantage of clearly marking a tubing interface.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Johnson as discussed with the expanded outside diameters as taught by Spencer in order to clearly mark an interface.

20. Regarding claim 21, Johnson discloses a connector system as previously discussed for claim 1, having a tube bypassing a filter (column 7, lines 47-59, especially lines 47-50 and Fig. 6, vent line 63 as labeled in Fig. 4).

21. Regarding claim 33, Johnson discloses the invention as substantially claimed, see above. However, Johnson lacks an expanded outside diameter as claimed [claim 29]. Spencer discloses an expanded outside diameter as discussed for claims 11 and 18. Regarding rationale and motivation, see discussion of claims 11 and 18.

22. Claims 3, 4, 7, 8, 20, 26-28, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US Patent 5,180,504) in view of Fell (US Patent 6,733,433).

23. Regarding claims 3 and 4, Johnson discloses a method of assembling blood treatment circuit as discussed for claims 1 and 2. Johnson lacks a plurality of secondary bags, a first tube connecting a primary bag to secondary bags and a third tube connecting secondary bags to each other. Fell discloses:

a plurality of secondary bags for holding stem-cells, plasma and red cells (column 6, lines 66-67 through column 7, lines 1-2, column 8, lines 59-63 and Fig. 3, elements 42-44 respectively);

a first tube connecting the primary bag to the plurality of secondary bags (Fig. 3, tubing between elements 46 and 47);

under sterile conditions (column 3, lines 19-24).

Fell further discloses a third tube connecting secondary bags to each other (Fig. 3, lines between elements 42, 43 and 44).

Fell discloses a treatment system for separating blood components (column 1, lines 15-22);

having a filter (column 6, lines 60-66 and Fig. 3, element 54).

Fell provides the ability to separate hematopoietic stem cells (column 2, lines 52-57). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the treatment system of Johnson as with the multiple bags and tubes of Fell as discussed in order to provide additional containers for blood components as provided by Fell.

Regarding the limitations of cutting and aseptically connecting second and third tubes, Fell substantially discloses a method of cutting and connecting tubes. Practicing this method on multiple tubes falls within the scope of obviousness.

24. Regarding claims 7 and 8, Johnson discloses a connector system, which substantially marks a connection position (column 6, lines 61-68 through column 7, lines 1-14 and Fig. 6, sterile connection devices 66a and 66b).

25. Regarding claim 20, Johnson discloses the invention as substantially claimed, see discussion of claim 1. However, Johnson lacks a plurality of secondary bags and a third tube to connect said secondary bags to one another as claimed [claim 20]. Fell discloses:

a plurality of secondary bags holding blood or blood components (column 6, lines 66-67 through column 7, lines 1-2, column 8, lines 59-63 and Fig. 3, elements 42-44 for holding stem-cells, plasma and red cells), and

a third tube to connect said secondary bags to one another (column 6, lines 60-66 and Fig. 3, tubing between stopcocks 45-48),

Fell provides the advantage of storing different blood components after a separation process (column 5, lines 20-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Johnson as discussed with the plurality of secondary bags and third connecting tube as taught by Fell in order to store different blood components separately.

Regarding the limitation of "by using an apparatus for aseptically connecting tubes," Examiner notes that the claim is directed to a filter, not a method of connecting. Regarding rationale and motivation, see discussion of claim 14.

26. Regarding claims 26 and 28, Johnson discloses a filter unit wherein said second tube has a mark that indicates the position of its connection to said third tube (column 6, lines 61-68 through column 7, lines 1-14 and Fig. 6, sterile connection devices 66a and 66b substantially indicating connecting position and correct connection).

27. Regarding claim 27, Johnson discloses the invention as substantially claimed, including a filter unit as discussed for claim 1. However, Johnson lacks a mark indicating the direction of flow of fluid as claimed [claim 27]. Examiner takes official notice that markings to show directional flow are well known in the art. Regarding rationale and motivation, see discussion of claim 9.

28. Regarding claim 30, Johnson discloses a filter unit having a by-pass tube that goes around a filter medium (column 7, lines 47-59, especially lines 47-50 and Fig. 6, vent line 63 as labeled in Fig. 4).

29. Regarding claim 32, Johnson discloses the invention as substantially claimed, see above. However, Johnson lacks two spaced apart marks as claimed [claim 32]. Examiner takes Official Notice that markings for guidance or positioning are commonly used in the art. Regarding rationale and motivation, see discussion of claim 9.

30. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US Patent 5,180,504) in view of Fell (US Patent 6,733,433), further in view of Spencer (US Patent 4,369,779).

31. Regarding claim 29, Johnson in view of Fell discloses the invention as substantially claimed, see above. However, Johnson in view of Fell lacks an expanded outside diameter as claimed [claim 29]. Spencer discloses an expanded outside diameter as discussed for claims 11 and 18. Regarding rationale and motivation, see discussion of claims 11 and 18.

32. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US Patent 5,180,504) in view of Spencer (US Patent 4,369,779), further in view of Minshall et al. (US Patent 5,496,302).

33. Regarding claims 12 and 13, Johnson in view of Spencer discloses method of assembling a circuit, comprising a filter as discussed for claim 1. Johnson in view of Spencer lacks a step of sterilizing a filter under different conditions with respect to a bag set. Minshall discloses a method of separately sterilizing components in a medical liquid handling system (column 2, lines 28-38). Minshall further discloses sterilizing a liquid handling component by irradiation (column 5, lines 55-57), and preferably sterilizing the liquid containers with steam heat (column 5, lines 51-54), to prevent deleterious effects of radiation on container contents (column 5, lines 48-50). Minshall uses a blood apheresis system as an example, without limiting the scope to apheresis systems (column 4, lines 52-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Johnson in view of Spencer as discussed for claim 1 with the method of sterilizing components separately as taught by Minshall in order to prevent deleterious effects.

Response to Arguments

34. Applicant's arguments with respect to claims 1-18, 20 and 21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich
Examiner
Art Unit 3761

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AMM

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